

## DETAILED ACTION

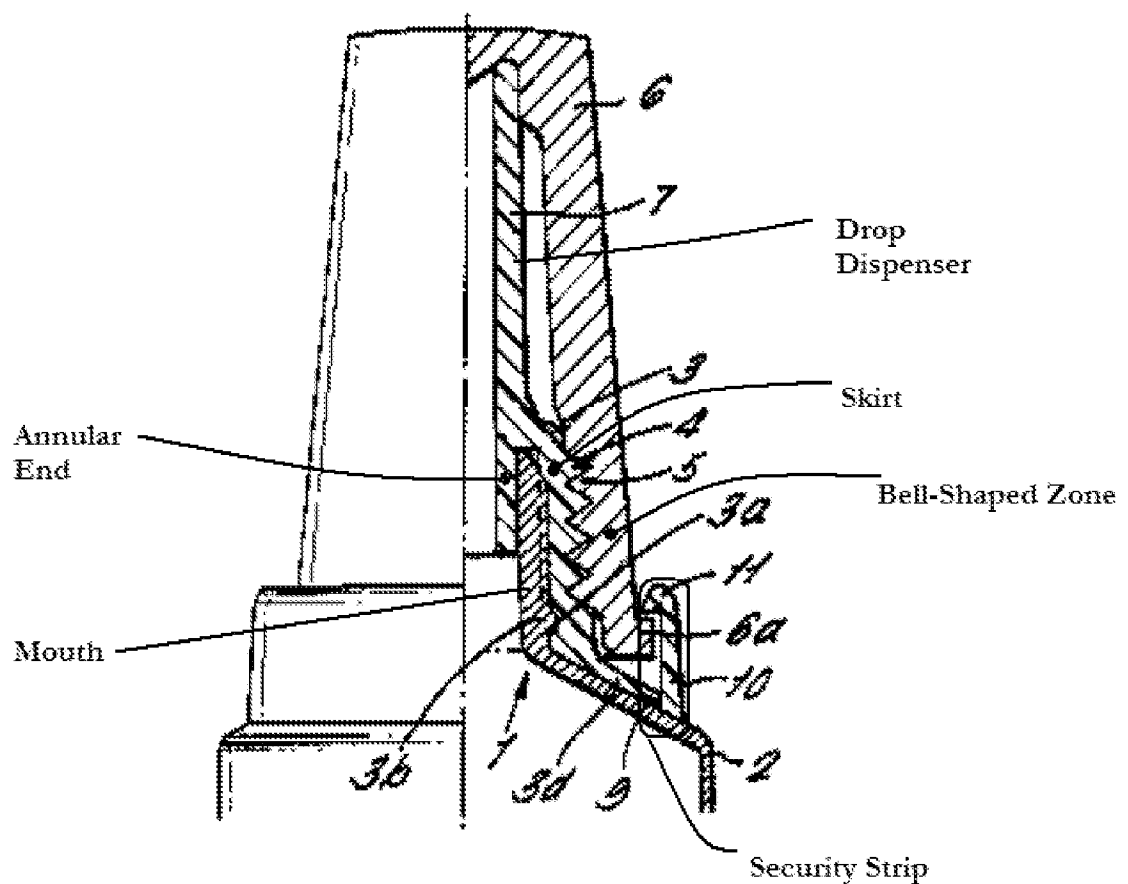
### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bosch (GB 2 263 107) in view of Kis et al. (US 2002/0020713).**

Regarding claims 1, 3 and 5, Bosch discloses a drop-dispenser including a container which in turn includes a flagon 2 for containing a product to be packaged, provided with a drop-dispenser and closed by a closure cap 6, wherein: the flagon 2 is provided with a mouth in which an annular end of the drop-dispenser is pressure-inserted; the drop-dispenser includes an appendix 7 for dosing the product, which appendix 7 projects externally of the flagon 2, and a skirt, external of and concentric to the annular end, which the skirt together with the annular end defines an annular cavity in which the mouth of the flagon 2 joints; means for fastening being located on an external surface of the skirt for removably fastening the closure cap 6 to the drop-dispenser (see marked-up figure 1).



**Marked-Up Figure 1**

Regarding claims 2 and 6, Bosch discloses the cap 6 includes a bell-shaped zone which covers the skirt of the drop-dispenser; the means for fastening including a screw-coupling 4/5 made partly on an external surface of the skirt and partly on an internal surface of the bell (see marked-up figure 1).

Regarding claim 7, Bosch discloses the cap 6 including an annular security strip connected to the bell-shaped zone by easy-break ribs 9 (see marked-up figure 1).

With further regards to claims 1-3 and 5-7, Bosch discloses all the elements of the claimed invention except a process for sterile packaging of the drop-dispenser.

Kis teaches a process for sterile packaging of containers with drop-dispensers, comprising stages of: sterilization of components of the container including a flagon or squeeze bottle, a drop-dispenser or nozzle tip and a closure cap; introduction of the components into an aseptic environment; filling of the flagon in the aseptic environment, insertion of the drop-dispenser on the flagon and closure of the flagon with the closure cap (see paragraphs 3 and 4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the drop-dispenser of the Bosch device with a process for sterile packaging, as taught by Kis, in order to fulfill conditions concerning sterility of the packaged pharmaceutical liquid or gel.

With respect to the limitations "wherein the process comprises a removable anchoring stage of the closure cap on the drop-dispenser, performed in non-sterile conditions, sterilization of the pre-assembled drop-dispenser-cap group and an introduction stage of the drop dispenser-cap group into the aseptic environment" Examiner notes it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the order of insertion of the components into the

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aseptic environment i.e. allowing sterilized components to enter the aseptic environment as a group or unit.

**Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bosch (GB 2 263 107) in view of Kis et al. (US 2002/0020713), as applied to claims 1-3 and 5-7 above, further in view of Odell et al. (US 6,792,743).**

Regarding claim 4, the combination of Bosch and Kis discloses all the elements of the claimed invention except a stage of sterilisation of the pre-assembled drop-dispenser-cap group is performed by inserting a plurality of the pre- assembled drop-dispenser-cap groups into a closed package and treating the closed package with gamma rays.

Odell teaches a process wherein a plurality of pre-assembled groups 12 are placed in a container or tub package 84, a closure or cover sheet 104 is then positioned to cover the package 84, the sealed package 82 is further sterilized by gamma rays or radiation in order to allow clean and sterile packaging of the pre-assembled groups 12 (see figure 5 and column 7, lines 6-49).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the drop-dispenser-cap groups of the combination of Bosch and Kis with a stage of sterilisation of the pre-assembled group performed by inserting a plurality of the pre- assembled groups into a closed package and treating the closed package with gamma rays, as taught by Odell, in order to allow clean and sterile packaging of the pre-assembled groups.

**Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bosch (GB 2 263 107) in view of Kis et al. (US 2002/0020713), as applied to claims 1-3 and 5-7 above, further in view of Strassenburgh (US 5,358,151).**

Regarding claim 8, the combination of Bosch and Kis discloses all the elements of the claimed invention except the appendix for dosing of the drop- dispenser includes on an external surface thereof, at least an annular cavity in which an annular relief is inserted when the cap is connected to the drop-dispenser; the annular relief being made on an internal surface of the cap.

Strassenburgh teaches a drop dispenser including an appendix 62 for dosing, wherein on the external surface is an annular cavity 60 in which an annular relief 58 made on the internal surface of the cap 48 is inserted when the cap is connected to the drop-dispenser providing an effective seal and securing of the cap with the appendix 62 (see figures 2, 3 and column 2, lines 6-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the combination device of Bosch and Kis with an appendix for dosing of the drop- dispenser which includes on an external surface thereof, at least an annular cavity in which an annular relief is inserted when the cap is connected to the drop-dispenser; the annular relief being made on an internal surface of the cap, as taught by Strassenburgh, in order to provide an effective seal and securing of the cap with the appendix.

Applicant should note that reference numerals throughout claims 1-8 do not represent a positive limitation. Therefore, reference numerals throughout the noted claims have not been given patentable weight.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mutterle (US 7,175,057), George (US 5,014,494), Willemstyn (US 6,893,428), Spada (US 7,178,703), Collado Bonet (US 5,314,085) and Leroy et al. (US 2006/0207912) show other sterile processes and dispensers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT K. NICHOLS II whose telephone number is (571)270-5312. The examiner can normally be reached on Mon-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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